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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,500	06/04/2001	John E. Ware	QMET-201	5112
24972	7590	01/27/2006	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			BLECK, CAROLYN M	
			ART UNIT	PAPER NUMBER
			3626	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/873,500	<b>Applicant(s)</b> WARE ET AL.	
	<b>Examiner</b> Carolyn M. Bleck	<b>Art Unit</b> 3626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,8-10,12-15,17-23,25-27 and 29-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-10,12-15,17-23,25-27 and 29-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Notice to Applicant***

1. This communication is in response to the amendment filed 10 November 2005. Claims 1-6,8-10,12-15,17-23,25-27 and 29-45 are pending. Claims 1, 10, 14, 17-18, 27, 34-35, and 39-40 have been amended. Claims 41-43 are newly added.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6, 8-10, 12-15, 17-23, 25-27, and 29-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ware et al. (Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures, The Quality of Life Newsletter, January 1999-April 1999), for substantially the same reasons given in the previous Office Action (mailed 18 October 2005), and further in view of Bair et al. (6,067,523).

- (A) Claims 1, 18, 35, and 39 have been amended to recite:

generating a customized test, "based on the patient's characteristics and one or more health domains selected by a patient or a health care provider"

the test having a plurality of questions for said patient in accordance with "said selected health domains"

dynamically modifying said test "based on an answer provided to an immediately prior question" if said estimated confidence level is outside a threshold

wherein "said threshold varies as a function of said estimated score."

As per these amendments, Ware discloses generating a customized test or dynamic assessment based on whether a patient is a headache sufferer (reads on "patient characteristics) (page 12, col. 3). Ware discloses dynamically modifying a test based on the immediately prior question (see Figure 3, page. 12, col. 1). As per the recitation of "the threshold varying as a function of the estimated score," Ware discloses the following steps in Figure 3: step 3 and 4) re-estimating the score, step 4) re-estimating the confidence interval, step 5) determining whether a stopping rule is satisfied and determining whether the score has been estimated within a preset standard of precision based on the confidence interval, wherein once the precision standard is met, the computer either begins assessing the next concept or ends the battery (considered to be a form of "threshold"), wherein the precision standard based on the confidence interval (i.e., the threshold) is set based on each patient's score (see page 12, col. 1-2). Note, Ware's discussion of where the preset standard of precision is +/- 5.4 for the lowest scoring patients, where these patients scored near or below an established cutoff point used in screening patients for psychiatric disorders. Note, that Ware discloses that the standard of precision was relaxed to +/- 7.9 or less for patients at or above the 90<sup>th</sup> percentile. (See page 12, col. 1 bottom to top of col. 2). It appears

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from this disclosure that Ware teaches that the threshold (i.e., precision standard based on the confidence interval) varies as a function of the estimated score.

Ware discloses the questionnaire or test pertaining to severity of headaches (pg. 12 col. 3 par. 1), general overall health (pg. 12 col. 3 par. 1), effectiveness of treatment, self-perceived status (pg. 12, col. 1-3 see mental health and headaches discussion, pg. 13 col. 1-2 see mental health discussion). These are forms of "health domains."

Ware does not expressly disclose the health domains being selected by a patient or a health care provider.

Bair discloses administering a questionnaire that is customized to a patient based on the specific treatment plan of each patient, wherein the treatment plan comprises questionnaires selected by a health care provider (i.e., therapist), wherein the questionnaires includes such areas as anxiety disorders, aggressiveness potential, and disability evaluation (Fig. 11, 17, col. 2 lines 58-65, col. 11 line 45 to col. 12 line 55). The areas of the questionnaire described above are considered to be a form of "health domain."

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Bair within the method of Ware with the motivation of providing tests or a series of tests at specified time intervals in order to monitor a patient's progress (Bair; col. 2 lines 5-10).

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(B) Claims 2-6, 8-9, 12-13, 15, 19-21, 22-23, 25-26, 29-33, and 36-38 have not been amended, and are therefore rejected for the same reasons given in the previous Office Action (18 October 2005), and incorporated herein.

(C) As per claim 10, Ware discloses estimating each person's score and confidence level based on their answers including analyzing the answers for systematic errors and quality (pg. 13 col. 1-2).

(D) As per claim 14, Ware discloses administering the dynamic assessment over a web browser and Internet or telephone (pg. 12 col. 3 par. 1-2).

(E) As per claim 17, Ware discloses the questionnaire or test pertaining to severity of headaches (pg. 12 col. 3 par. 1), general overall health (pg. 12 col. 3 par. 1), effectiveness of treatment, self-perceived status (pg. 12, col. 1-3 see mental health and headaches discussion, pg. 13 col. 1-2 see mental health discussion).

(F) Claim 27 repeats the limitation of claim 10, and is therefore rejected for the same reason as claim 10, and incorporated herein.

(G) Claim 34 repeats the same limitations as claim 17, and is therefore rejected for the same reason as claim 17, and incorporated herein.

(H) Claim 40 repeat method and system claims 1, 6, 17, and 18, and is therefore rejected for the same reasons as those claims.

(I) As per claim 41, Bair discloses Bair discloses administering a questionnaire that is customized to a patient based on the specific treatment plan of each patient, wherein the treatment plan comprises one or more questionnaires selected by a health care provider (i.e., therapist), wherein the questionnaires includes such areas as anxiety disorders, aggressiveness potential, and disability evaluation (Fig. 11, 17, col. 2 lines 58-65, col. 11 line 45 to col. 12 line 55). The areas of the questionnaire described above are considered to be a form of "at least two health domains."

(J) As per claims 42-45, Bair discloses:

(a) administering the test before a variable is introduced, wherein said variable includes a pharmaceutical such as Zoloft or Xanax, interventions or therapies (Fig. 1, 29-31, 27B, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14);

(b) readministering the questionnaire after the variable is introduced (Fig. 1, 16, 29-31, 27B, col. 6 lines 11-21, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14, col. 15 lines 15-51); and

(c) comparing resultant data obtained from each separate administration of said test, wherein said resultant data is indicative of efficacy (see "patient satisfaction and assessing treatment in order to gauge the effect of the treatment upon the behavioral problem) or impact of the introduction of said variable on said health status or health

care of said patient (Abstract; Fig. 29-31, 27B, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14, col. 15 lines 15-51).

The motivation for including the features of Bair within the method and system of Ware being to assess treatment and patient satisfaction (Bair; col. 15 lines 20-30).

### ***Response to Arguments***

4. Applicant's arguments filed 10 November 2005 have been fully considered but they are not persuasive. Applicant's arguments will be addressed below in the order in which they appear in the response filed 10 November 2005.

(A) In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 10 November 2005 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Ware and/or Bair, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (18 October 2005), and incorporated herein.

One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).



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In addition, it is respectfully submitted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

### ***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (571) 272-6767. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (571) 272-6776.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**7. Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks  
Washington, D.C. 20231

**Or faxed to:**

(571) 273-8300 [Official communications]

(571) 273-8300 [After Final communications labeled "Box AF"]

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(571) 273-6767 [Informal/ Draft communications, labeled  
"PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to the Knox Building, Alexandria, VA.



CB

January 12, 2006

  
JOSEPH THOMAS  
SUPERVISORY PATENT EXAMINER